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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,073	08/26/2003	Steven E. Hobbs	137	4654

32763 7590 12/01/2006

NANOSTREAM, INC.
C/O INTELLECTUAL PROPERTY/TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,073

Applicant(s)

HOBBS ET AL.

Examiner

Natalia Levkovich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08/26/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION***Election/Restriction***

1. Applicant's election with traverse of claim group I (claims 1-21 and 26-30) in the reply dated 08/30/2006 is acknowledged. The traversal is on the grounds that the inventions of claim groups I and II are not independent (since they are related) and that examination of claim groups I and II would not place an undue burden on the Examiner. This is not found persuasive because, while the inventions are related as apparatus and method of making (assembling), the method can be used independently, as was discussed in the prior Office Action, for example, for assembling devices having a different structure. Examiner notes that 'independent' does not mean absence of relationships. For example, Great Britain and USA are independent yet related entities / countries. Examiner also notes that, as was previously shown, groups I and II are classified in different classes and corresponding searches would require different strategies. Therefore, examination of groups I and II would be indeed an undue burden to the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-21 and 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11 and 26 recite: a 'plastically deformable outer layer'. The limitation is unclear since 'plastically deformable' is a relative characteristic of a material. In fact, every solid substance can be 'plastically deformed' provided a sufficient deforming force is applied.

Claim Rejections - 35 USC § 103

4 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1—11, 14-21 and 26-30 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Staats (US 7060227).

Referring to claims 1-2, 11, 14 and 26, Staats discloses microfluidic assemblies comprising, as shown, for example, in Figure 4, a first microfluidic substrate 40 with a microchannel / aperture (not indexed) parallel to the outer surface of the substrate; a second substrate 70 ['retractable element' – Ex.] with a second aperture and protrusions ['raised features' – Ex.] 60, the second aperture and the protrusions forming a mating surface and means for compressing the two substrates together. "Mechanical pressure such as one exerted by a clamp ['actuator' – Ex.] over the alignment features may be sufficient to secure the two substrates together to form a liquid-tight seal" (Col.4, lines 3-5).

Although Staats discloses multi-layered micro-fluidic devices, the reference does not specifically teach coated surfaces / 'outer layers'. However, such layers are routinely used in the art, especially in planar technologies. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed outer layers / coatings in the modified apparatus of Staats, in order to obtain surfaces with desired physical / chemical characteristics.

With respect to claims 3 and 15, Staats teaches in column 13, lines 10-13, that the disclosed microfluidic structures can perform "operations such as liquid chromatography, electrophoresis and the like".

Referring to claims 4, 6 and 17, Staats discloses some polymeric substrate materials, such as PMMA, as being usable in the art "because of its optical clarity in the

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visible wavelengths making it suitable for laser induced fluorescence (LIF) detection” (Col.2, line 35).

Regarding claim 5, Staats teaches adhesive bonding in column 3, lines 60-65.

In reference to claims 7, 16, 18 and 30, Staats teaches polyethylene and polypropylene in column 9, lines 40-45.

With respect to claims 8 and 19, Staats does not teach the mating surface being made of a material having hardness greater than the hardness of the corresponding coating / outer layer. However, the use of harder structures for making impressions / ‘plastically deforming’ in softer materials is notoriously well known. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed protrusions of higher hardness (relative to the one of a corresponding surface to be mated with), in the modified apparatus of Staats, in order to provide a tighter sealing for the device.

Regarding claims 9 and 20, Staats teaches “plunger or piston-like structures” in column 7, lines 35-40.

Regarding claims 10 and 21, Staats does not teach sensors, however, microfluidic devices comprising position or compression sensors are commonly employed in the art. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed such sensors in the modified apparatus of Staats, in order to control the quality of sealing.

7. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staats in view of Paul et al. (US 20040011648).

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Although Staats is concerned with providing reliable sealing and discloses the pressure-driven fluid flow in micro-fluidic devices to be very well known, the reference does not teach the apparatus to be employed at elevated pressures and, therefore, to include sealing means capable to withstand such pressures (in particular, up to 500 psi). Paul discloses microfluidic flow devices which "include: a wide variety of different micro-components" and can incorporate "a high integrity seal that can withstand pressures in excess of 500 psi required for chromatographic separation and/or chemical processing" – (see [0061]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized the sealing means in the modified apparatus of Staats such that the seal would withstand the high pressure, in order to enhance the scope of applicability of the device.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:


Lum et al. (US 5932315) – discloses microfluidic assemblies with mating surfaces.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700